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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,161	RALPH, PETER	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 November 2004*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-20,22-27,29-42 and 44-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-20,22-34 and 46* is/are rejected.

7)☒ Claim(s) *3, 35-42, 44-45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 11/1/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2, 6, 21, 27, 43, 47-62 are cancelled.
2. Currently, claims 1, 3-5, 7-20, 22-27, 29-42, 44-46 are under examination.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claim 39, recites "wherein said humanized version of recombinant 4D5 anti-HER2 antibody is transtuzumab (HERCEPTIN)". There is no support for the wording "transtuzumab" in light of specification. Similarly, claim 41 and 42 suffer the same problem.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-5, 7-20, 22-42, 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (c), line 3, "with a labeled secondary antibody recognizing said analyte" is vague and indefinite. It is not clear whether this labeled secondary antibody binds only the portion of 'analyte" or both "analyte" and the complex of the second antibody and the bound analyte.

With respect to claims 39, 41-42, where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular antibody detected in the instant method.

With respect to claim 39, 41 and 42, it is not clear what is the wording "trastuzmab".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3-5, 7-20, 22-34, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al. (US 5518887) in view of Nishimura et al. (US 4803154).

Parson et al. teach an immunoassay for simultaneously measuring different analytes in a tested sample. Parson et al. teach that immobilizing dual antibodies on a solid support to detect analyte and its structurally related substance, e.g. interference (Col. 5, line 1-15; line 50-65; Col. 6, line 10-28). The dual antibodies comprising a first antibody recognizing the analyte as free analyte and a second antibody recognizing said analyte interference when bound to said analyte (Col. 5, line 50-56). Parson et al. teach using this dual antibody format for detecting the presence or quantifying the amount of the target analyte in the presence of interfering substance in the test sample, e.g. determining the total amount of free analyte and interference bound to the analyte (Col. 5, line 1-15).

However, Parson et al. do not teach using a detectable labeled antibody as a detection means to measure the analytes in a test sample.

Nishimura et al. teach ELISA immunoassay by either using enzyme-labeled antibody to increase detection sensitivity (Col. 2, line 25-45; 6, line 27-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Parson et al. with the suitable enzyme-labeled antibody for detecting means as taught by Nishimura et al. since ELISA immunoassay for detection target molecules in a test sample is well-knonw and incorporating labeled antibodies are frequently used to perform in ELISA assay.

With respect to claims 4-5, 25-27, Parson et al. teach that the first and second antibodies can be either polyclonal or monoclonal antibodies (Col. 3, line 40-52; Col. 6, line 25-45).

With respect to claim 7-12, 30-34, Nishimura et al. teach using peroxidase and alkaline phosphatase as the enzyme-substrate for detection means (Col. 6, line 27-34).

With respect to claim 13, Nishimura et al. teach immobilizing antibodies on a solid support, such as well or beads (Col. 1 to Col. 3; See Introduction).

With respect to claims 14-15, Parson et al. teach that the solid support includes colloidal metals, gold, particles, or glass fiber (Col. 6, line 49-55; Col. 13, line 20-29).

With respect to claims 16-17, Parson et al. teach that the test sample can be from body fluid or serum (See Example 1-8).

With respect to claims 19-20, 22-24, Parson et al. teach that the analytes can be of polypeptide antigen, antibodies (monoclonal or polyclonal), receptor, drug, hormone, enzymes, or erythrocyte cells (Col. 2, line 45-60; Claims 11, 13-18).

Response to Applicant's Arguments

8. Applicant's arguments with respect to claims 1, 4-6, 13-21, 23-29, 34 and 46 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

9. Claims 3, 35-42, 44-45 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The following is an examiner's statement of reasons for allowance: no prior art teaches or fairly suggests providing a solid surface dual coated with an anti-HER2 first antibody and an anti-HER2 ECD second antibody to determine the amount of total HER2 analyte in a sample by comparing a standard curve generated with various purified analyte. The closets prior art is the reference of Baselga et al. (J. Clin. Oncology (1996) Vol. 14: 737-744) where Baselga et al. teach using 4D5 monoclonal antibody measuring the HER2 ECD, but not at the same time simultaneously measuring the HER2 to determine the total amount of the HER2 in the patient's serum.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

January 18, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/04/05